

REMARKS/ARGUMENTS

Prior to amendment Claims 1-32 were pending in the application - they are still pending.

Claim 1 as amended and in Claims dependent thereon, recite:

a catheter center member having **three** sections, each extending for “at least a compressed stent length,” and

a sheath having **two** section members each extending for “at least a compressed stent length.”

The catheter (**center member**) has in series from the distal end of the catheter:

- 1) a compressed stent retention section (extending for at least a compressed stent length),
- 2) a stent plunger,
- 3) sheath retraction section (extending for at least a compressed stent length),
- 4) a fixed seal mount, and
- 5) a fluid receiving chamber section (extending for at least a compressed stent length).

The catheter **sheath** has in series:

- 1) a stent retention portion having an inner surface has a lubricious quality,
- 2) a stent retraction portion having a smooth inner surface different from the first material, and
- 3) a movable seal mount.

The geometric arrangement of the middle member where two of three “compressed length sections” provides a catheter spacing length (sheath retraction section 80) to contain, for example anti-kink elements, between the compressed stent retention section 78 and the fluid receiving chamber section 74 (as seen in Figure 3). The geometric requirement of using different materials on the inner surface of the sheath in different length sections is combined with the geometric spacing along the catheter needed to

provide a leak free seal against the moving inner surface of the sheath. The presence of a spacing length (sheath retraction section having at least a compressed stent length) between the compressed stent retention section and the fluid receiving chamber section to prevent damage to the inner surface of the sheath as needed for sealing is not suggested or disclosed by the prior art.

The use of a loose spring or helical spring having a particular cross section or multiple washers as an anti-kinking element surrounding a catheter section between two fixed end structures (the stent plunger and fixed mount) provides a structure which when that catheter section is linear, provides no axial load carrying capabilities, while acting as a radial spacer to prevent deflection of the sheath wall inwards toward the catheter centerline. Such a loosely contained anti-kinking spacer readily allows the catheter to bends freely while substantially preventing the wall of the surrounding sheath from buckling towards the center member (catheter). As the sheath surrounding the anti-kink containing catheter section is bent, the looseness (spaces/gaps) in the spaces between loose windings of a spring or spaces between loose disc or washer type elements will diminish, such that depending on sizing and geometric configuration the anti-kink elements on the inside of the bending radius will touch and prevent further bending. As the bending of the catheter is taking place, the anti kinking spacer will continue to maintain a minimum radial distance (space) between the catheter center member and the surrounding sheath which will reduce if not eliminate the likelihood of kinking of the outer sheath.

Such structures are not disclosed or suggested by the cited prior art.

Objections to the Disclosure

The Examiner has objected to wording in Claims 5, 15, and 31. These claims have been amended to overcome this objection.

35 U.S.C. §103(a) Rejections

Claims 1, 11, 23 and 24 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fiedler (US Patent 5,817,101), in view of Luckic et al. (US Patent 5,709,703).

Claim 1, 11, 23, and 24 have been amended to recite dimensional limitations in combination with geometric and material quality relationships that are not disclosed or suggested by the prior art, as discussed above.

The Examiner combines the Fiedler and Luckic references without any suggestion or motivation to do so. The Examiner's characterization of the scratch protection tube of Luckic to be included in the structure of Fiedler, is not consistent with the definitions of words as would be understood by a person of ordinary skill in the art as pictured and described in the specification (including the drawings). A metal radiopaque scratch protection tube cannot be not reasonably classified as having a lubricious surface. The coefficient of friction for a lubricious surface is known to be approximately 0.2, while a metal as disclosed in Luckic would have a coefficient of friction of 0.3 and possibly greater. The Examiner states that it would have been obvious to combine Fiedler and Luckic and to choose the "rigid stop 37" of Luckic to prevent it from migrating proximally. Since Fiedler already has a stop (seal means) 38 the selection of the Luckic stop 37 to add another stop is unexplained. Combining Fiedler, a fluid actuated stent delivery system with Luckic, a linear force actuated stent delivery system, by picking and choosing components to include without some suggestion or teaching to do is using 20-20 hindsight to the prior art to arrive at an unjustified rejection. Taking selected elements from each reference is like choosing from a parts list which is not allowed. There must be some suggestion or teaching to combine the elements as done by the Examiner. There is none. Further, the Claims as amended recite geometric, dimensional, and materials qualities relationships, as discussed above, that are not shown or discussed in the prior art. The disclosure of Fiedler seemingly acknowledges the problem of sealing or pressurizing fluid leakage as addressed by embodiments according the current invention, by disclosing the solution of sealed bellows structures 102, 130, 140, which in effect teaches away from further efforts at providing a better more reliable sealing arrangement for the fluid pressurizing cavity. A sealed bellows eliminates such seals and the leakage issues associated with surface scoring and sealing altogether.

Claims 28-32 have been rejected under 35 U.S.C. §102(e) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Randall et al. (US Patent 6,514,261).

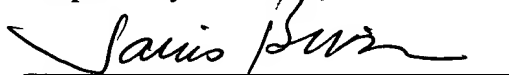
Claims 28-32 have been amended to recite structures fixed to the central catheter member on either axial side of the spacer to provide an axially loose as well as radially loose fit for the spacer. The disclosure of Randall et al. is limited to a spring through which the axial force to a floating plunger 28 is transmitted to oppose the stent retraction force exerted on the stent as the sheath is retracted. In a configuration according to the present invention, except in extreme angles of bending and binding, no axial force is carried or transmitted by a spacer according Claim 28 as amended. Claims 29-32 are dependent on Claim 28 as amended and have also thereby been amended. The Examiner's comments with respect to rejection of those claims are considered moot, and the many of the structures disclosed in the specification and recited in the claims are not analogous to the "spring" pictured and described in Randall et al..

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 566-1888.

Aug 19, 2005

Respectfully submitted,



Janis J. Biksa

Registration No. 33,648

Attorney for Applicant

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
Facsimile No.: (707) 543-5420